

LIGHTWRITER® SL40

TECHNICAL INFORMATION

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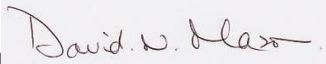
EC DECLARATION OF CONFORMITY

Toby Churchill Limited; Norman Way, Over, Cambridge, CB24 5QE, declare under our own responsibility that:

- the **Lightwriter® SL40** range of equipment as described within the technical documentation file referenced TF4, conform to the requirements of Directive 1999/5/EC concerning Class I radio equipment and telecommunications terminal equipment and
- Council Directive 93/42/EEC concerning medical devices as amended by Directive 98/79/EC, Directive 2000/70/EC & Directive 2001/104/EC for Class I devices.
- is in conformity with the provisions of the Directives applicable to Class I equipment by conforming with Harmonized Standards as listed but not limited to the following:
- EN12182; EN 14971; EN 60529; EN16201; EN60601-1; EN 60601-1-1;
- EN 60601-1-2; EN301 511; EN 301 489.
- the requirements of Annex I, Annex VII and Annex IX have been followed for Class I medical device and registration requirements of Article 14 have been notified to the UK Competent Authority.
- the Declaration covers equipment/devices manufactured from the period commencing April 2008 and until such time as a renewed conformity declaration is raised;
- this declaration covers the equipment/device family range with its accessories including charger, keyguards, mounting system and carry case listed below and includes the software embedded within the hardware.

Lightwriter® SL40

This declaration is signed on behalf of Toby Churchill Limited by:

| | |
|-----------|---|
| Signed |  |
| Name | David Mason |
| Authority | Director |
| Date | December 2009 |

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Contact us if you have any further questions. Our mailing address is: Toby Churchill Ltd., Toby Churchill House, Norman Way Industrial Estate, Over, Cambridgeshire, CB24 5QE, UK.

Statement of Intended Use

- The Lightwriter[®] SL40 is intended to be used as an augmentative communication device for people with speech impairment. It is intended to be used as a portable unit or as a freestanding unit on a table or other similar support or as a wheel chair mounted unit.
- The buzzer is not to be relied upon as an alarm for life- or safety-critical use.

GENERAL CONDITIONS OF USE

- The Lightwriter[®] SL40, charger and most accessories have been subjected to extensive quality control and test procedures to ensure compliance with the essential requirements of the Medical Devices Directive (MDA), and the National Health Service Purchasing and Supplies Agency specification for Electronic Assistive Technology. These tests include the simulation of fault conditions, in order to confirm the design and manufacturing process, and to ensure the safety of users of our equipment.
- The Lightwriter[®] SL40 should not interfere with the correct operation of adjacent electronic equipment. Appropriate E.B.M.E. staff must confirm their safe use in critical areas such as Intensive Care Units.

General Description And Classification

CLASSIFICATION

The Toby Churchill Ltd Lightwriter® SL40 range of Aids and associated software are considered to be medical devices because the intended purpose is to:

- compensate for lack of speech due to injury or handicap;
- to provide a means of communication for those where this would be difficult or impossible, due to injury, handicap or motoric physical disability;
- to provide environmental control functions.

The intended user typically might suffer from acquired speech loss following laryngectomy, tracheostomy, head injury, stroke, or with progressive neurological diseases such as Motor Neurone Disease (ALS), Parkinson's Disease, Multiple Sclerosis or Huntington's Chorea.

The devices are classified as a Class I device by virtue of Rule 1 and Rule 12 and that no other rules apply.

DESCRIPTION

The Lightwriter® SL40 range provides speech and augments loss of speech, infra-red control signals to assist independence for those with restricted physical movement and built-in mobile phone. These control signals can operate power sockets, light switches, etc. Various methods of input control can be used. Input keyboard details: Keysize 1.1 cm, Key spacing 0.4 cm between keys, total size of keyboard 21_ x 5.6 cm, required keypress pressure 71 g.

See Point of Sale information for full details

Ingress of Fluids

- The Lightwriter® SL40 is splashproof but not waterproof. To prevent accidental damage to this electronic equipment, avoid fluids entering inside the case. If accidental spillage of fluid over the unit is likely to occur, it may be advisable to cover the unit with a flexible transparent membrane such as polythene or Clingfilm.
- When cleaning the unit please follow the instructions in the User Guide.
- The Lightwriter® SL40 operates at low voltage, and there is no risk of electric shock if the unit becomes wet.
- If the Lightwriter® SL40 becomes wet, it should be powered off and allowed to thoroughly dry before attempting to use again.

Safety Precautions

- If the Lightwriter® SL40 is used as a portable unit then the harness that is available from Toby Churchill Ltd should be considered. If the harness is not used the Lightwriter® SL40 must be held securely so that it cannot fall. A fall may result in damage to the Lightwriter® SL40 or in personal injury.
- If the Lightwriter® SL40 is freestanding it may be supported on a suitable stand. Due consideration must be given to the stability of the unit. Care must be taken that any cables connected to the Lightwriter® SL40 or to an external power supply are secured or placed so that:
 - They cannot be trapped in any way which could damage a cable.
 - A cable cannot be accidentally pulled which could result in the Lightwriter® SL40 or the power-supply falling.
 - Cables and connectors must not be put under strain by putting them under tension or by bending the cable sharply.
- Care must be taken in the selection of input switches, accessories and printers. It is recommended that only Toby Churchill Ltd accessories are used with a Lightwriter® SL40.
- Connectors for switches, printers etc are fitted with black plastic covers. These should be refitted whenever the connector is not in use.
- The external speaker socket must not be used to connect the Lightwriter® SL40 to any externally powered amplification system, e.g. Public Address systems.
- Input switches which have removable cables should not be used.
- If the Lightwriter® SL40 is wheel chair mounted it must be fitted securely to the wheel chair so that it cannot become loose.

ACCESSORIES

- We recommend that Toby Churchill Ltd accessories should be the first choice as they have been specifically designed to work with the Lightwriter® SL40. However other accessories may be used providing they are compatible with the Lightwriter® SL40. If other than genuine Toby Churchill Ltd accessories are used, assessment of any associated risk is the responsibility of the installer. As a guide, the recommended switch input devices specification is:
 - 3.5mm mono jack plug.
 - Removable jack plug to jack plug cables are prohibited from use.
 - Screened input cable.
 - Cable length shall be the minimum necessary.
 - Surplus cable to be secured carefully away from risk of mechanical damage.
- Accessories shall comply with EN60950, or EN60601-1-1.

CHARGER

- Our chargers are approved to EN60950. In addition we inspect and test them to ensure user-safety, in accordance with EN60601-1-1.
- Use of non- Toby Churchill Ltd chargers is not recommended, and may cause a hazard and/or damage the Lightwriter® SL40. We have taken every precaution to avoid a fire-risk in this circumstance, but cannot accept responsibility should this occur. If you need to use any other supply, for example: an external battery, obtain approval for the use of the supply from Toby Churchill Ltd before using it.
- The charger lead should be safely positioned in order to avoid hazards.

PLUG-IN DEVICES

- Refit the blanking plugs to all connectors after use.
- Plug-in devices (including the cabling) should be suppressed in order that the complete Lightwriter® SL40 and peripheral and/or plug-in switches and/or plug-in speakers meets CE standards.
- All cable leads should be safely positioned in order to avoid hazards.
- Input switches that have removable cables should not be used.

MOUNTING

- The therapist or carer is RESPONSIBLE FOR THE SAFETY of mounting-systems for the Lightwriter® SL40 and the switches where these are mounted.
- The stability of a wheelchair may be affected (where the Lightwriter® SL40 is mounted on the wheelchair and is swung to the side when transferring in or out of the chair).
- The Lightwriter® SL40 must be mounted so that the wheel chair is stable for all positions of the Lightwriter® SL40 and its mount, particularly while the wheel chair is in motion.
- If an external battery unit is used it must be mounted securely and in such a position as to enhance the stability of the wheel chair.
 - Any cables connected to the Lightwriter® SL40 must be positioned and secured so that:
 - They cannot be trapped by any part of the wheelchair where they could be crushed or cut.
 - They are not subject to abrasion by moving parts.
 - They do not impede the movement of the Lightwriter® SL40 mount.
 - They are not liable to be snagged by objects external to the wheel-chair.
 - The cables and connectors must not be put under strain by putting them under tension or by bending a cable sharply.
- In the UK it is recommended that the Toby Churchill Ltd mounting system be used.
- If the Lightwriter® SL40 is used in any other way due consideration must be given to the security and stability of any mount and the safety of any cables and connectors.

TRAVEL CARE WARNING

- Hard objects in front of passengers or loose in a vehicle could be dangerous in the event of emergency braking. Therefore, we recommend that if you remain in a wheelchair when travelling in a vehicle, lift the mounting pole out of the mounting-block complete with your Lightwriter® SL40 or other communication-aid, and stow the assembly securely so that it cannot easily become dislodged. See MDA document No. DB 2001 (03).

ENVIRONMENTAL CONDITIONS

- **Water and other liquids:** the Lightwriter® SL40 should not be exposed to heavy rain. Use in very light rain is possible. If there is ingress of water or other liquid into the Lightwriter® SL40 the system should be allowed to dry before use.
- **Humidity:** the Lightwriter® SL40 should not be exposed to conditions where condensation can occur inside the case. Usually when the system is operating it will not be affected by humidity but it should not be left for long in very humid conditions, for example in a bathroom or swimming pool. If condensation does occur when it is not operating it should be allowed to dry before switching it on.
- **Temperature:** the Lightwriter® SL40 can be operated in ambient temperatures in the range 0 C to 30 C. Note that the temperature may be outside this range if the Lightwriter® SL40 has been left in a vehicle exposed to the sun or to cold temperatures, in which case it should be allowed to reach a safe temperature before operation.

MULTIPLE PORTABLE SOCKET-OUTLETS

- This section specifies the requirements for the construction of a safe system, when installed with other equipment in a home, hospital, or other residence.
- This sub-section refers to mains extension socket-strips.
- The socket-strip should be wall-mounted, not be placed on the floor.
- Cables should be protected from traffic (foot or wheelchair wheel),
- Cables should be securely clipped; there should be no risk of tripping, or pulling the equipment onto the floor.
- Socket-strips should not be daisy-chained; each socket-strip should be plugged into the wall.
- Extension-reels should not be plugged into the socket-strip.
- Care must be taken not to exceed the rating of the socket strip, or of the wiring of the ring-main. Lightwriter® SL40 chargers are rated at 17VA, and will not present an overload problem.
- The socket-strip should only be used for supplying power to equipment which is intended to form part of the system. Other equipment will be connected entirely at the installer's risk.
- The connection of non-approved accessories to the socket-strip may constitute a hazard to the patient under fault-conditions. A risk assessment is recommended in these circumstances.

EN60601

- The Lightwriter® SL40 meets the essential requirements of EN60601.
 - **Earth Leakage**
All readings below 5 μ A
 - **Enclosure Leakage Current**
All readings below 2 μ A
 - **Patient Leakage Current**
All readings less than 45 μ A
 - **Patient Auxiliary Current**
All readings less than 40 μ A
- The Lightwriter® SL40, together with accessories provided by Toby Churchill Ltd, are suitable for use within the PATIENT ENVIRONMENT; other accessories are not approved, and are to be used at the installer's risk.

FURTHER READING

- www.doh.gov.uk/ DOH (Dept of Health)
- www.nhs.uk/ NHS
- www.medical-devices.gov.uk/ MDA
- www.medical-devices.gov.uk/ > search for 'DB' > Device Bulletins 2001 > MDA document No. DB 2001 (03) "Guidance on the Safe Transportation of Wheelchairs"
- www.doh.gov.uk/scg/communityequipment.htm Community Equipment
- www.becta.org.uk/cap/ BECTa

Decontamination

The Lightwriter® SL40 and associated equipment may become dirty through a variety of means such as saliva, mucus, spilled food and drink, and from contact with dirty hands.

There may also be a need to decontaminate equipment to reduce the risk of infection transmission.

CLEANING PROCEDURE

- The recommended cleaning procedure is to wipe the affected external surfaces with a cloth moistened in hot water with some washing-up liquid, and use a nail brush for more stubborn dirt.
- The Lightwriter® SL40 is splashproof but not waterproof. Do not allow water to enter inside the Lightwriter® SL40. It is recommended that you turn the Lightwriter® SL40 on end with the charger point lowest and to clean the Lightwriter® SL40 in this position, reducing the risk of any water entering inside the Lightwriter® SL40.
- If the Lightwriter® SL40 is fitted with a LightTouch keyboard, this may be dismantled by removing the 2 screws in the keyguard after which the keyguard and the 48 keys can then be lifted off (check first that you have a User Guide handy to show you how to replace the keys in the right order!) The keyguard and 48 plastic keys can be soaked in water and given a more thorough cleaning. Ensure the plastic keys and keyguard are dry before re-fitting.

DECONTAMINATION PROCEDURE

There may be a requirement to decontaminate a Lightwriter® SL40 and/or associated equipment after use to reduce the risk of infection transmission to other people. The Central Public Health Laboratory (a division of the Department of Health in the UK) has recommended the following decontamination procedure for this type of low-risk equipment:

- Clean the external surfaces with a disposable paper wipe moistened with warm detergent solution. (see Cleaning Procedure)
- Allow the surfaces to dry.
- Wipe the surfaces with a commercially-available alcohol-impregnated disposable wipe.
- Note that this equipment should not be sterilised, nor should disinfecting fluids be used as these may attack the plastic materials, and can make the transparent display filters go opaque.
- **CAUTION:**
 - Do not immerse equipment in water
 - Do not use disinfecting fluids (such as surgical spirit, Hibitane (a brand name for chlorhexidene) or Cidex (a brand name for 2% alkaline-buffered glutaraldehyde)
 - Do not autoclave equipment or expose to elevated temperatures

CARRY BAG

The Carry Bag cannot be decontaminated, and should be disposed of if cross-infection is a possibility

